PSJ14 Janssen Opp Exh 64 – JAN-MS-02960654

Controlled Substances Suspicious Order Monitoring (SOM) Program Questionnaire

Section VI-C: Suspicious Order Monitoring Program – Flagged Orders

51	When you encounter suspicious order(s) how do you review, clear, escalate, or report them? Do you have special reviews for the higher abused drugs or do all scheduled drugs see the same scrutiny?	We contact the customer regarding the order, than make a decision if to clear. Special reviews are used for higher abused drugs, but we review all scheduled drugs
52	Who has the authority to clear an order of suspicion?	Compliance Mgr. or President
53	Are records maintained to document all investigations? How are they maintained and filed?	YES x NO ☐ Maintained in the customer's file.
54	If an order is flagged, what is the average investigation time? Do you contact the customer to understand the order size to determine if there is a reason?	Same day or next day, depending in when order was placed. Yes, we contact the customer.
55	Do your SOM investigators visit your customers? If so, what is the ratio of on-site visits by investigator to phone calls?	YES x☐ NO ☐ Annually, sometimes more if warranted.
56	Do repeated flagged orders from one specific customer warrant an on-site visit by your compliance group?	YES x☐ NO ☐
57	Who (title and position) reports the suspicious orders to the DEA?	Compliance Mgr. and President
58	How are the orders reported (electronically, via telephone, etc)?	Electronically
59	Is the suspicious order filled or suspended?	Filled x☐ Suspended x☐ Both
60	Does the company reduce an order and ship the balance?	YES x☐ NO ☐
61	How many suspicious orders were reported to the DEA during the last 12 months?	8

Controlled Substances Suspicious Order Monitoring (SOM) Program Questionnaire

Section VI-C: Suspicious Order Monitoring Program – Flagged Orders

62	When these orders involve JOM products at what point in the process would you notify JOM?	We do not notify manufacturers. We notify the DEA and the state pharmacy boards.
63	Would an order ever be flagged as suspicious if it is within threshold limits? If so, please explain.	YES x NO ☐ If it was unusually large for a daily purchase.

Section VI-D: Suspicious Order Monitoring Program – Other

63	Does the company have policies regarding illegal drug use? If so, explain.	YES x NO ☐ Defined in our personnel manual
64	Does the company do random and/or for cause drug screenings on employees?	All new employees
65	Does the company provide training to employees regarding drug abuse trends, including published high abuse areas?	Yes
66	Does the company do specific employee training regarding its SOM system?	Yes
67	Do you train your sales organization/account managers on the SOM red flags?	Yes
68	What % of your customers do you perform on-site visits?	100%

Section VII: Signature

Name	Title	Date
James Barclay	Compliance Mgr.	October 15, 2014

Miami-Luken DEA Compliance Procedures Manual

Revised August 20, 2013

Index

Section 1

DEA Regulations

Compliance

DEA Regulations Compliance

Narcotic Vault combination

The combination to the Narcotic Vault should be changed periodically. The Warehouse Manager and the Warehouse Supervisor should do this together.

(1) The Warehouse Manager and the Warehouse Supervisor should assure that no one else is nearby when the vault is being opened to keep the vault combination a secret

(2) Any employee who has a security code should not make it known to anyone else or write it anywhere it might be found.

Narcotic Vault Security

Keys to the Vault day gate and Cage keys must be locked up at night. They should never be left where they are accessible to other employees.

Narcotic Customer Shipments and Returns

Salesmen and Warehouse employees must be extremely careful when writing customer returns for controlled substances to make sure the items are completely and accurately written.

Controlled substances may never be left sitting out of the cage or vault overnight. Customer orders containing controlled items must be locked up overnight. Incoming manufacturer shipments must have the controlled substances pulled out and locked up overnight, *even if they have not yet been checked in by the Receiving Department.*

Boxes of customer's returns must be checked as soon as they arrive at the warehouse to make sure there are no controlled items mixed in with the regular merchandise.

Alarm System Test

The alarm systems must be tested at least once each quarter. The test date and the employees doing the test must be noted in a permanent Log book that DEA can review. Any problems with the system and when they were corrected must be documented.

Cage and Vault Scanning Orders

Anytime there is a problem scanning an order or finding an error that must be corrected to get the order cleared off the screen, the merchandise must be manually checked against the order documents item by item to make sure that a new error has not been created trying to clear out the first error. This must be done for cage items and vault narcotics.

Cage and Vault Inventories

DEA requires that all inventories show the date and time of the day when inventories are taken. This should include regular mid-month and month-end inventories. It also includes special inventories of items being moved into cage or vault for the first time when they become controlled items. The name of the persons doing the count and recount must be shown on the inventories also. Note whether the inventory was at the opening of business or close of business. Keep the C-II's on a separate listing from the C-III, C-IV an C-V listing.

Annual Arcos Inventory

Each year, the annual Arcos Inventory must be entered and sent to D.E.A. by January 15th. This inventory is reported from the physical count made on the prior December 31st each year after the end of business. The D.E.A. provides further processes, which must be followed, for the Annual Arcos Inventory.

1. Inventories not identified: If the Year-end inventory is submitted with the Final Activity report of the year (December report), an indication must be made on the Submission Control Form that the inventory is also enclosed.

2. Improper codes used: The only transaction code used for Year-end Inventories is Option 3.

3. Improper Date: The only date reported for Year-end Inventories is December 31st (12/31).

4. Multiple Inventories: Each NDC product code must be reported only once on the Year-end Inventory, reflecting the total quantity on hand of that product on December 31st. Reporting two or more lines for the same NDC product on the Year-end Inventory is not allowed.

5. Date and Time-of-Day: DEA requires that all inventories show the date and time-of-day when inventories are taken.

6. Employee Identification: The name of the persons doing the count and recount must be shown on the inventories.

DEA and State Registration Expiration Date Verification

Miami-Luken shall verify customer's DEA registration expiration date and State Pharmacy License expiration date by requesting annually copies of the customer for us.

Section 3 describes the new process established in December 2010 for obtaining and verifying customer and vendor licenses.

Biennial Inventory

In order to satisfy the legal requirements of DEA for taking and filing a complete biennial cage and vault inventory, the following Procedure should be followed:

Reproduce a copy of the December 31, (Past Year) Physical Count Sheets for the cage and vault. Mark this copy "Biennial Inventory" and store it in a separate file folder marked, "DEA Biennial Inventory". We will do this every December 31st so that the technical requirements will have been met. This inventory is not sent to DEA, it is only kept on file.

The actual physical counting of the cage and vault are always performed by the night shift manager assisted by the night shift person who works in the cage and vault. The cage and vault counts must be done after the end of business on the last day of the month.

Security

The most critical area of operations is security. Twenty four hours per day and seven days each week we record by video camera controlled substance storage areas. The C-II vault is opened only on the day shift to minimize access. All controls including cage and C-II vault products are counted every fifteen days to check and see if there is a shortage. All C-II items are bar code scanned to assure no errors occurred during the order or picking process.

There are video cameras that record other important warehouse areas including the picking line, packing area and receiving department.

The alarm system is state of the art and includes door contacts and motion detectors in both office and warehouse areas. When the master alarm control box is activated it will detect and insolate the specific location that fails to set up.

Section 2

Pharmacy Customers Controlled Substance Profile

M-L Pharmacy Controlled Substance Profile

Store Name: _____

Location: _____

_____

Store Owner/Responsible Pharmacist: _____

How long in business under current ownership: _____

1. Are you located in or within a 5 mile radius of one or more medical facilities such as a hospital or large clinic? (check all that apply)
   Physician Offices: ☐ Medical Clinics: ☐ Hospitals: ☐
   Long Term Care Facilities: ☐ Hospices: ☐ Pain Clinics: ☐

2. How many of each is in your general market area? Clinics _____
   Hospitals _____ Long-Term Care Facilities _____

3. What type of clinic (s) do you service? Use back of page.

4. List names and addresses on back of page.

5. List top 5 doctors that are prescribing Oxycodone and Hydrocodones in your market area? _____

6. What is the usual # of tablets dispensed for a single prescription? 30 Day _____
   90 Day _____

7. What is the percent of cash business for the products mentioned in questions 5 & 6? _____

8. List names and addresses of doctors noted in question 5. Use back of page.

9. Are all prescriptions filled by your store generated by "local" doctors? _____

10. Does your pharmacy have an internet website? _____

11. Are you affiliated with an internet pharmacy facilitator or any other pharmacy internet site?
    _____

12. Do the doctors referred to in question 7 see patients routinely? Is there a Patient Doctor Relationship established? If the answer is "no" please explain.
    _____
    _____
    _____
    _____

13. How are prescriptions delivered by your pharmacy?
    Customer Pick up _____ What % _____
    Store deliveries _____ What % _____
    Via Mail _____ What % _____

14. Has your Pharmacy, current owner and/or any Pharmacist had any disciplinary or corrective action (i.e. FDA issues, DEA registration or state license suspended, revoked, fines imposed, etc...) within the past 10 years? ☐ Yes ☐ No

If yes, for each corrective action please provide the following (attach additional sheets details if necessary).

Individual/Business Name	Date of Action	Description of Action/Explanation
a)		
b)		
c)		

15. Do prescriptions from pain management clinics (written by their affiliated physicians) represent more than 30% of your Pharmacy's controlled substance business? ☐ Yes ☐ No

16. How many total prescriptions does your pharmacy fill during an average month?_____

a) Of your total average monthly prescriptions, how many are for controlled substances?_____

b) How many are for Schedule II items? *_____

c) How many are for Schedule II-V items? *_____

17. Please list the top four suppliers (your primary wholesaler and three others) where you purchase pharmaceutical products and indicate the total percent of purchase from each. The total percentage should equal 100%.

Supplier Name	Total Rx%

I declare that the foregoing is true and correct.

Signature (DEA License Holder) Title(DEA License Holder) Date

Name (please print)

Continuation of page 1

3. Type of clinics served:

4. Names and addresses of clinics

6. Names and addresses of Doctors

Section 3

Customer and Vender License Verification

Customer and Vendor License Verification

The Process for obtaining customer state pharmacy licenses will include the following:

(1) A copy of the new state license will be obtained from each customer prior to the expiration date of their current license.

(2) We will go on-line to check the State Pharmacy Board license file to verify that the renewal has been issued.

(3) Failure to find verification will result in a phone call to the State Pharmacy Board and suspension of sales to the account on advice from the State Pharmacy Board.

We will continue to require copies of DEA certificates prior to expiration of the current certificate from both customers and vendors. These will be verified on-line monthly to assure that the certificates are still valid.

PROCEDURES FOR UPDATING CUSTOMER AND VENDOR DEA LICENSES

CUSTOMERS:

New Customers:

Salesmen will obtain a copy of the customers DEA license as part of the required document package for setting up a new customer. The DEA license information will be checked against the DEA Website and a confirmation document printed – *see attached instructions*.

Persons Responsible: Jim Barclay, Sharon Dearing, and Steve Fullarton.

Existing Customers:

The first week of every month a computer list will be printed showing all customers DEA licenses that will expire at the end of the month – *see attached sample*. The listing will be given to the persons responsible for checking the licenses against the DEA Website. Each license will be checked on-line at http://www.justice.gov/dea/ and a confirmation document printed – *see attached instructions*. These documents will be given to the persons responsible for updating the Customer Master file.

Persons Responsible for Checking: Brenda Fiseus, Karen Linbaugh.

Persons Responsible for Updating: Steve Fullarton, Cindy Willet, Sharon Dearing, and Jim Barclay.

VENDORS:

New and Existing Vendors:

The first week of every month a computer list will be printed showing all vendors DEA licenses that will expire at the end of the month – *see attached sample*. The listing will be given to the persons responsible for checking the licenses against the DEA Website and updating the Vendor Master file. Each license will be checked and a confirmation document printed – *see attached instructions*.

Persons Responsible for Checking and Updating: Cindy Willet, and Barbara Lanham.

Central filing:

All DEA License Confirmation Documents will be given to the responsible person for cataloging and filing.

Person Responsible: Receptionist.

UNITED STATES
DRUG ENFORCEMENT ADMINISTRATION

Search dea.gov

Press Room
News Releases
Speeches & Testimony

About Us
Mission
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DEA Museum
Office Locations

Careers at DEA

DEA Drug Information

Law Enforcement

Drug Prevention

Diversion Control & Prescription

Drug Policy

Legislative Resources

Publications

Acquisitions & Contracts

Got Drugs?

Turn in your unused or expired medication for safe disposal
SATURDAY, SEPTEMBER 29, 10AM – 2PM
CLICK HERE FOR MORE INFORMATION

Alleged International Narcotics Trafficker Extradited from Colombia on Cocaine Importation Charges

Defendant Allegedly Conspired to Import 8.3 Tons of Cocaine into the U.S. in One Shipment

August 8 (NEWARK) - U.S. Drug Enforcement Administration (DEA) Special Agent in Charge of the New Jersey Field Division, Brian Crowell; DEA Special Agent in Charge of the Miami Field Division, Mark R. Trouville; United States Attorney for the Southern District of New York (SDNY), Preet Bharara; United States Attorney for the Southern District of Florida (SDFL), Wifredo A. Ferrer; and Assistant Director in Charge of the New York Office of the Federal Bureau of Investigation, Janice K. Fedarcyk, today announced the extradition of Doily De Jesus Cifuentes-Villa from Colombia to the United States to face separate charges in both the Southern District of New York and the Southern District of Florida. She is charged with conspiring to import multi-ton quantities of cocaine into the United States. Cifuentes-Villa, a citizen of Colombia, arrived in the Southern District of New York yesterday and was immediately transferred to the Southern District of Florida, where she made her initial appearance in court today before Magistrate Judge John O'Sullivan and was detained pending trial.

Read the Full Story >>

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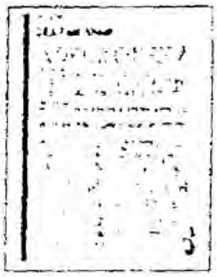

U.S. Department of Justice, Drug Enforcement Administration

Office of Diversion Control

Registration

Registration

- For Registration Help - DEA Registration.Help@usdoj.gov
  Please be sure to include your DEA Registration number in your email
- Applications
- Registration Tools
- Registration Resources

Applications

- **NEW DEA NUMBER ASSIGNMENT**
  Due to the large Type A (Practitioner) registrant population, the initial alpha letter "B" has been exhausted. DEA will begin using the new alpha letter "F" as the initial character for all new registration for Type A (Practitioner) registrations (11/09/2008)
- Renewal Applications
  - DEA Form 224a – Renewal Application for Retail Pharmacy, Hospital/Clinic, Practitioner, Teaching Institution, or Mid-Level Practitioner
  - DEA Form 225a – Renewal Application for Manufacturer, Distributor, Researcher, Analytical Laboratory, Importer, Exporter
  - DEA Form 363a – Renewal Application for Narcotic Treatment Programs
  - DEA Form 510a – Renewal Application for Domestic Chemical
- New Applications
  - DEA Form 224 – New Application for Retail Pharmacy, Hospital/Clinic, Practitioner, Teaching Institution, or Mid-Level Practitioner
  - DEA Form 225 – New Application for Manufacturer, Distributor, Researcher, Analytical Laboratory, Importer, Exporter
  - DEA Form 363 – New Application for Narcotic Treatment Programs
  - DEA Form 510 – New Application for Domestic Chemical

Registration Tools

- Chain Renewals
- Duplicate Certificate
- Duplicate Receipt of Registration Application
- Online Pharmacy Modifications
  - Modify business activity from Retail Pharmacy to Retail Online Pharmacy
  - Modify business activity from Retail Online Pharmacy to Retail Pharmacy
  - Modify existing Retail Online Pharmacy information
- Official Order Forms
- Large Volume Order Forms
- Registration Categories and Fees
- Registration Changes
  - Address Changes
  - Drug Code Changes
  - Name Changes
  - Schedule Changes
- Registration Procedures
- Registration Validation ← Click On This

DEA Registration Validation Login:

Important: Please enter *your* DEA information to login (not the DEA # you are attempting to validate)

DEA Number (Required - Not Case Sensitive)
PM0031550

Last Name or Business Name (Required - Not Case Sensitive)
As it appears on your registration. Example:
If "Smith, John Q MD" is on your registration, then enter: Smith
If "Smith's, Pharmacy" is on your registration, then enter: Smith's
If "Smith's Pharmacy" (no comma) is on your registration,
then enter: Smith's Pharmacy
Miami-Luken

SSN (Required if given on application)

Tax ID (Required if given on application)
316019589

The U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control maintains registrant data and is considered the primary source of information on DEA registrants. The website https://www.deadiversion.usdoj.gov is the offical location for real time online verification.

Login ← Click On This

DEA OFFICE OF DIVERSION CONTROL PRIVACY POLICY

U.S. Department of Justice • Drug Enforcement Administration

Office of Diversion Control

DEA Registration Validation:

DEA Number to be validated (Required - Not Case Sensitive)

AT8334447

Validate ← Click On This

Logout

Office of Diversion Control

DEA Registration Validation Result:

DEA Number: AT8334447

Name (Last, First): TRIVILLIAN'S PHAR OF KANAWHA ,

Business Activity: RETAIL PHARMACY

Business Address 1: 215 35TH STREET, SE

Business Address 2:

Business Address 3:

City: CHARLESTON

State: WV

Zip: 25304

Schedules: Schedule II Narcotic, Schedule II Non Narcotic, Schedule III Narcotic, Schedule III Non Narcotic, Schedule IV, Schedule V

Expire Date: 11-30-2014

The U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control maintains registrant data and is considered the primary source of information on DEA registrants. The website https://www.deadiversion.usdoj.gov is the offical location for real time online verification.

DEA Registration Validation:

DEA Number to be validated (Required - Not Case Sensitive)

Validate

Logout

Click on "Logout" when done

Or

Click on "Validate" to review

another customer or vender

Customers Needing
New Expiration Dates

Cust #	Customer Name	DEA License	Exp Date
009917	FAMILY DRUG WHEELWRIGHT	AF1972656	12/09/30

Sample Customer
Report

Vendors Needing
New Expiration Dates

Buyer	Vendor #	Vendor Name	DEA License	Exp Date
LANHAMB	371	GENENTECH, USA/ROCHE	RG0403307	12/09/30
WILLETC	367	G. AND W. LABORATORY,INC	PG0113441	12/09/30

Sample Vendor
Report

Section 4

Sample Letters Requesting Copies of State and DEA Licenses From Customers and Venders

REQUEST FOR NECESSARY INFORMATION FOR PROCESSING CII ORDERS

Date: 3/27/13

Dear Customer:

Our records indicate that we are in need of a copy of your Power of Attorney for your Account. We need to know who is authorized to sign your CII orders.

Please return immediately by mail or Fax (937) 743-7786 to my attention or e-mail: tmoberly@miamiluken.com

Failure to respond will cause a delay in shipment of controlled substances.

Copy of your current DEA Registration Certificate (_____) (Required by Code of Federal Regulations)

Thank you,

Teresa Moberly
Registration Clerk

REQUEST FOR NECESSARY INFORMATION FOR PROCESSING ORDERS

Date: 8/14/12

Dear Customer:

Our records indicate that we are in need of the information below. Please return immediately by mail or Fax (937) 743-7786 to my attention or e-mail: tmoberly@miamiluken.com.

Failure to respond will cause a delay in shipment of controlled substances.

Copy of your current DEA Registration Certificate (FE1808546) (Required by Code of Federal Regulations)

Thank you,

Teresa Moberly
Registration Clerk

REQUEST FOR NECESSARY INFORMATION FOR PROCESSING ORDERS

Date: July 2, 2012

Dear Distributor:

Our records indicate that we are in need of the information below. Please return immediately by mail or Fax (937) 743-7786 to my attention so orders will not be delayed.

Copy of your current Distributor DEA Registration Certificate ( ) (Required by Code of Federal Regulations)

- Please specify name of Manufacturer.

Thank you,

Teresa Moberly
Registration Clerk

REQUEST FOR NECESSARY INFORMATION FOR PROCESSING ORDERS

Date: July 2, 2012

Dear Distributor:

Our records indicate that we are in need of the information below. Please return immediately by mail or Fax (937) 743-7786 to my attention so orders will not be delayed.

Copy of your current **State Board License ( )** (Required by Code of Federal Regulations)

- Please specify name of Manufacturer.

Thank you.

Teresa Moberly
Registration Clerk

Section 5

Pharmacy Customers

Controlled Substance

Returns Handling

Handling Returns

Conditions/Restrictions Regarding Returns from Hospitals and Institutions

Under FDA regulations, returns of overstocks and outdated prescription items directly to Miami Luken from hospitals and other institutions, such as nursing homes, are not permitted. Accepting these returns is a criminal violation. Hospitals and other institutions must contact the manufacturer directly about outdated and overstocks for return authorization and then return the shipment directly to the manufacturer.

Miami Luken is allowed by law to accept prescription returns of shipping errors only from hospitals and institutions, if done within 10 days. Our policy is two working days for error notification. Please refer to form, "Vendor/Institutional Prescription Error Return Notification".

Returns of hospital or institution shipping errors must be processed according to the following process: The manufacturer must be advised of any returns of errors of RX items shipped. The Vendor Return form must be completed and sent to the manufacture whenever a hospital or institution returns a shipping error of a prescription item. A copy of each form should be kept on file.

Procedure for Processing Returns from Retail Pharmacies

1. In order for retail customers to initiate the product return process, they must either transmit a list of overstock and outdated returns or call damages and shorts to a Miami-Luken Customer Service Representative for authorization of the return. Drivers are not permitted to pick up customer returns unless they have written authorization from Miami-Luken. This policy is to protect the customer by making sure the credit for the return is assigned correctly. This also provides further safeguard to see that the returned items are correctly returned to the Miami-Luken Returns Department.

2. Paperwork for merchandise that has been shipped back to a manufacture will continue to be filed in an alphabetic file. A Manufacturer Return Invoice must be prepared before merchandise can be shipped back to a manufacturer. Only Miami-Luken Return Invoices should be used for processing customer returns. One copy should be included with each shipment back to a manufacture and one copy filed according to the process that follows. Debit memo numbers are system generated on the invoice.

3. A Manufacturer Return Invoice should be prepared through the computer before requesting return authorization from the manufacturer. The Manufacturer Return Invoice is computer generated through the system from customer outdated returns or short dated merchandise and pulled from Miami-Luken inventory.

   The following information must be on every return form:
   Customer name, address and account number.

For each line item include:

(a) Miami-Luken item number (from sticker)
(b) Quality of pieces returned
(c) Grade code (R, O, M)
(d) Description of item (complete name)
(e) Form (tabs, Capsules, Syrup, etc)
(f) Size of package (100's, Pint, Case of 24, etc)
(g) Strength (25mg, 500mg, etc)

If controlled substances are being returned they should be packed together in a paper bag and identified as Controlled substances so they can be pulled from the returns box and put into the cage. Controlled Substances are to be processed the same day they are returned. Controlled Substances must be listed on a separate credit return form in order to facilitate processing. A copy of the credit return is given to the customer and a copy is given to the Senior Buyer.

Once the return invoice has been prepared, additional items should not be added to the return. If additional items are to be written up when the Manufacturer Rep comes in, a separate Manufacturer Return Invoice for these items must be processed, and a new debit memo number assigned.

A Debit Memo Number should be on all invoices according to the following guidelines:

A. Debit memo numbers assigned to manufacturer returns must show a separate number for every separate return invoice total. Multiple manufacture return invoices for one manufacture must not be combined under a single debit memo number.
B. Manufacture return invoices should have a debit memo number assigned and printed on the invoice.

Examination of Customer Returns

A. Products returned from customers will be carefully examined to determine the condition and disposition. The product must be in perfect condition before it can be returned to the saleable stock shelves. This means it must be clean and show no external damage. The outer safety seal must be intact if one exists. The cap should be removed, if possible, to make sure the inner seal is still in place and shows no tampering.

B. The expiration date of each product must show more than nine months dating left on the product. Return from customers that have less than six months time remaining before they expire should NOT be put back on the shelf in the inventory. Put them in them in the morgue to be returned to the manufacturer. Miami-Luken normally pulls items off the shelves with less than six months remaining before expiration and puts them in the morgue.

C. It is necessary to look for other markings such as "Professional Sample", "Sample", "Not for Resale", or other similar words. This type of merchandise from retailers will not be accepted for credit. Miami-Luken does not sell products with these labels.

C-II Returns

Customer returns of C-II controlled substances require special handling. Initially a customer requests authorization to return a C-II product. The customer is sent a "Miami-Luken C-II Return Form" which he completes in full detail. The form is returned to the Miami-Luken senior pharmaceutical buyer. If the form is complete the Miami-Luken buyer writes a 222-C narcotic order blank and has the appropriate copies delivered to the customer. The customer then is permitted to make the return of the C-II product to Miami-Luken.

Miami Luken

Opt Source

C-II RETURN FORM

CUSTOMER ACCT.#: _____ **NAME:** _____

*Exp. Date must have at least 1 yr. dating

NAME OF DRUG	SIZE	QUANTITY	INVOICE# OR DATE PURCHASED	NDC#	EXP. DATE

FAX COMPLETED FORM TO 888-884-4793 ATTN: BRENDA OR CINDY

Outdated, Damaged and Unsaleable Products

(1) All prescription products that are unsaleable because of being outdated, damaged, mis-branded, deteriorated or in opened containers, will be stored in a separate morgue area away from the regular picking and storage racks.

(2) The morgue are will be separated from the main warehouse with limited access and will be clearly marked with signs stating "Out-of-Date and Unsaleable Products." The morgue cage door will be locked when morgue personnel are absent.

(3) Products returned from customers and the disposition. The product must be in perfect condition before it can be returned to the saleable stock shelves. This means it must be clean and shows no external damage. The outer safety seal must be intact if one exists. The cap should be removed, if possible, to make sure the inner seal is still in place and shows no tampering. Finally, there must be more than six months dating left on the product. If all of these requirements are met then the product can be returned to the shelf.

(4) Products that do not meet all of the above requirements will be moved to the morgue area where they will be stored in the appropriate manufacturer box.

(5) Refrigerated products returned from customers will be placed in the morgue always regardless of condition. Except if the return is received in an insulated container and is still at a cold temperature and meets all of the inspection requirements.

(6) A procedure for periodic checking of the inventory for outdated or short-dated products will be followed. Items found with less than four months dating should be pulled and moved to the morgue. Details of this procedure are shown in the "procedures" section.

(7) The controlled substance outdated and unsaleable items will be stored in the cage and in the vault. Separate morgue areas will be stored in the cage and in the vault. Separate morgue areas will be designated apart from the regular picking shelves. These will be marked with signs identifying them as out-of-date and unsaleable products.

Section 6

Pre-Screening of C-II Orders For Suspicious Quantities

Pre-Screening of C-II Orders For Suspicious Quantities

C-II orders arrive two ways. Hand written blanks sent in by customers and CSOS printed blanks that are transmitted by customers. All blanks are screened manually before the orders are entered into the computer and picking documents generated.

Screening is performed by designated senior people who have years of experience seeing C-II order blanks. Their knowledge of each customer store size and ordering habits allow them to recognize and question unusual order quantities. Also, they recognize newer accounts and order quantities that look unusual as compared to orders received from regular customers.

Should an order quantity appear to be potentially suspicious by one of the senior people, will be discussed with another one of the senior people. They will review the history of controlled purchases by that account and possibly call the customer for verification and clarification. If they still question the order quantity it will be reviewed with the company President for a decision.

Should the decision be made to not ship the item and reduce the order quantity to zero, DEA would be contacted and advised of the customer and the circumstances. The contact with DEA would be made by the Company President or a person he delegates to make the call.

The current senior people who pre-screen C-II order blanks for suspicious quantities include: Cindy Willet – Senior Rx Buyer

Brenda Fiscus – Senior Customer Service

Barbara Lanham – Senior Rx Buyer

Section 7

An Overview of Customer Monitoring For Potentially Excessive Purchases

An Overview of Customer Monitoring for Potentially Excessive Purchases

Orders for prescription products can only be filled for active customers. Before customers become active they must under go checks for valid State and DEA licenses, plus credit checks. A potential account who is approved as active is entered in the master customer file and becomes eligible to place orders.

Large quantity prescription orders will be monitored by the warehouse picking employees. The order line is flagged for the buying department who arranges a call back to the customer to verify the desired amount. Should unusual quantity orders for an item by the same customer continue to occur the item is further reviewed to see if it falls into the area of potentially abused drugs.

Controlled substance potentially excess orders are monitored more critically than non-controls for suspicious orders. Schedule II blanks or CSOS transmitted schedule II orders will have lines reduced or deleted if suspicious. Month end controlled substance usage reports are studied and potentially excessive customer purchases are reported to DEA. Specific procedures for determination of suspicious C-II order quantities are shown in Section 6.

Potentially excessive orders of prescription drugs, non-controlled or controlled substances are reviewed by the company President, the chief pharmaceutical buyer, the chief Financial Officer and the Vice President of Sales. Consideration is given to the order quantity relative to typical orders by the base of all pharmaceutical customers. The history of purchases by the involved customer, the type of drug and the known illegal use of that drug and prior history of the involved customer relative to questionable activities will be reviewed for actions to be taken.

The decision to contact the State Board of Pharmacy and DEA must be made and the call made within three working days.

All customers are required to provide to us a current State Pharmacy License and a current DEA license. Each year we request copies of their new licenses thirty days prior to the expiration date of the current licenses on file. Shipments cease to a customer on the date their State License or DEA license expires.

Anytime we become suspicious of customers involvement in criminal activity notification is given to the Ohio State Board of Pharmacy, DEA and local police departments.

See Section 8 of this manual for a description of reports and procedures that assist in making evaluations of pharmacies whose history of controlled drug purchases makes them suspect for further study and or action.

See Section 9 of this manual which describes the "Suspicious Order Monitoring System". It evaluates every item line ordered each day before the computer system allows it to either be entered as legitimate order or rejects it as a "suspicious" order quantity

See Section 6 for special pre-screening procedures for all C-II orders before they are accepted into the order entry system.

Section 8

Procedures For Tracking Controlled Drugs

PROCEDURES FOR TRACKING CONTROLLED DRUGS

1. Reports are generated daily on selected pharmacies showing amount and percentage of controlled drugs purchased.
2. Reports are generated monthly on pharmacies purchasing over 3000 tablets of any family of controlled drugs.
   a. Reports show percentage of controlled drugs purchased against total drugs purchased for each pharmacy.
   b. Reports show percentage of controlled drugs purchased against total controlled drugs purchased.
3. Monthly reports are reviewed for any excessive controlled drug purchases.
   a. If any excessive controlled drug are suspected by a pharmacy, reports are requested from the individual pharmacy showing the physicians writing the prescriptions and at least the city of residence of the patient receiving the prescription.
   b. The report is reviewed to determine if any action is to be taken on the individual pharmacy, i.e., the suspension of purchasing controlled drugs.
   c. The DEA and State Pharmacy Board are notified of the receipt of the pharmacy reports and will be made available if requested.
   d. After reviewing reports received from an individual pharmacy and additional internal reports, and a decision is made to prohibit that pharmacy from purchasing controlled drugs, the pharmacy is immediately notified shipments of controlled drugs are suspended or reduced in quantity.
   e. The DEA and State Pharmacy Board are notified when an individual pharmacy is prohibited from purchasing controlled drugs.
   f. Should any of the above problems occur within Warren County the Warren County Drug Task Force will be notified also.

MONTHLY CONTROLLED ITEMS

MONITORING REPORTS

"Control Pct":

Every customer that is able to purchase controlled items is listed on this report. The total dollar purchases of all items, the total dollar purchases of controlled items, and the percent of controlled item purchases to all purchases is shown for each customer.

"Susp by Cust":

Every customer that purchased 3000 or more pills of an item that falls in one of the Monitored Classes *(see attached list)* appears on this report. The total pills purchased for the named item and all equivalents of that item appears for each customer, for all customers, and the percent of customers pills to all customers pills. The total dollars purchased for each customer is also shown.

"Susp by Item":

This report shows the same information as the "Susp by Cust" but sequenced differently. The sequence is Named item and Customer in descending number of pills.

Miami-Luken Inc

SAMPLE CLASSES
MONITORED

CLASS	TITLE
DP	ANTINEOPLASTIC AGENTS
EK	SKELETAL MUSCLE RELAXANTS
GR	04 NONSTEROIDAL ANTI-INFLAMMATORY AGENTS
GS	08 OPIATE AGONISTS
GT	12 OPIATE PARTIAL AGONISTS
GU	92 MISCELLANEOUS ANALGESICS & ANTIPYRETICS
HA	04 BARBITURATES
HB	08 BENZODIAZEPINES
HG	92 MISCELLANEOUS ANTICONVULSANTS
HJ	04 ANTIDEPRESSANTS
HZ	RESPIRATORY & CEREBRAL STIMULANTS
JC	04 BARBITURATES
JD	08 BENZODIAZEPINES
JE	92 MISCELLANEOUS ANXIOLYTICS, SEDATIVES, & HYPNOTICS
NU	ANTITUSSIVES
RF	ANTIDIARRHEA AGENTS
TE	ADRENALS
TJ	ANDROGENS

Section 9

Suspicious Order Monitoring System

Suspicious Order Monitoring – An Outline

Miami-Luken has described in Section 7 and Section 8 procedures used for monitoring customer controlled substance purchases. These are important checks that alert us to customers who may order only one or two pieces each day, which quantities might fall below daily order limits, but exceed monthly limits.

Miami-Luken has developed a suspicious order monitoring system, described here in Section 9 that looks at each order quantity prior to accepting the order. It looks at the item ordered as part of a Medication Family. The quantity ordered, using all quantities for the same Medication Family is analyzed based on month to date totals and on established month to date limits. The computer makes the immediate decision to accept or block the item ordered.

Following are the specific details of this "Suspicious Order Monitoring System".

MIAMI-LUKEN

SUSPICIOUS ORDER MONITORING SYSTEM

OVERVIEW:

After building a profile for each Customer they are entered into the monitoring system. The system is designed to limit the amount of certain Medication Families that individual Customers can buy during a month. When a Customer attempts to buy an amount that exceeds their maximum quantity of a Medication Family the shipment is stopped and an alert is put out. There are many factors that are considered in the process of building a Customer Profile.

SYSTEM

There are four databases that drive the system.

- The Medication Family File consists of the following fields:
  - Medication Family Code.
  - Item Number that is a member of this Medication family.
  - Number of Units (i.e. pills etc.) in this Number.
  - Item Description.
- Maximum Units per Month for Customers File consists of the following fields:
  - Medication Family Code.
  - Customer Number.
  - Maximum Units per Month for this Medication Family and Customer Number.
  - New Customer Flag.
- Item History for the Current Month consists of the following fields:
  - Shipped Item Number.
  - Medication Family Code.
  - Quantity Shipped
  - Number of Units

- Units Shipped.

- Event Log File consists of the following information:

- A record showing each attempt to exceed a maximum amount

- A record for each Customer for each Medication Family showing units sold this month and units available for this month.

ORDER PROCESSING:

If an Order in progress has an item number in the Medication Family File for a customer that would exceed the maximum number of units shipped for the current month, the item would not be shipped and an explanation "Max qty Exceeded" would be printed on the invoice. An entry would be made to the event log.

Note: A Sample of Drug Classes Monitored is attached

Miami-Luken Inc

SAMPLE CLASSES
MONITORED

CLASS	TITLE
DP	ANTINEOPLASTIC AGENTS
EK	SKELETAL MUSCLE RELAXANTS
GR	04 NONSTEROIDAL ANTI-INFLAMMATORY AGENTS
GS	08 OPIATE AGONISTS
GT	12 OPIATE PARTIAL AGONISTS
GU	92 MISCELLANEOUS ANALGESICS & ANTIPYRETICS
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RF	ANTIDIARRHEA AGENTS
TE	ADRENALS
TJ	ANDROGENS

Section 10

ARCOS Reporting

Procedures - Overview

MIAMI-LUKEN INC.
ARCOS REPORTING PROCEDURES

All purchases, sales, and returns of Scheduled items are controlled and tracked by the Order Processing and Inventory Control Systems. Miami-Luken maintains a perpetual inventory of all items.

Controls:

The Customer and Vendor Master files contain fields for DEA License Numbers and Expiration Dates. No purchases, sales, or returns can be processed for Scheduled items without an unexpired license. Current copies of DEA Licenses are maintained on file. Various Reports alert staff members responsible to request a new DEA License when necessary.

The perpetual inventory of all Scheduled items is checked by cycle counting twice a month. Any discrepancies are researched documented and reconciled by the Buyers.

All transactions processed for Scheduled items are saved in a computer file. An Ending Inventory for each item is written to this file on the last day of each month. This file is never purged.

Arcos Reporting:

Shortly after the end of a month the Senior Buyer begins the process of reporting all Schedule II and Schedule III transactions to the DEA Arcos Unit that occurred during the previous month.

The first step is to run a report that shows any Scheduled item that is out-of-balance according to the transactions that have been saved during the previous month. These discrepancies are rare but they do occur. An example would be, if our receiving department receives an order by mistake it is saved in the computer file the same day. The error is picked up on a cycle count and the perpetual inventory is corrected. The receiving transaction is still in the save file causing the ending inventory to be off in the save file. The Buyer deletes the receiving transaction from the save file and documents the explanation. The Buyer then reruns the out-of-balance report until no item is shown.

The next step is to run a report showing the detail of all transactions for every Scheduled item. Then run a Summary report of the Arcos items.

At Calendar Year End the Year End Inventory Report is run and the Year End file is sent.

All these reports are saved in a binder and stored in the cage along with copies of the CII order forms.

The person in the IT department responsible for sending the Arcos report runs a process to convert the Arcos file to the required format (see Arcos Registrants Handbook). The file is then sent electronically via the Arcos Unit's https site. An Upload report from this transmission is printed and given to the Buyer to be filed with the rest of the reports.

The brown copies of the CII forms are mailed to the Arcos Unit with a Return Receipt Request. When the Receipt is returned it is filed along with all the other documents.

Section 11

Section 11 has been deleted

Section 12

Miami-Luken DEA

Compliance

Miscellaneous

DEA Regulations And Miami-Luken Responsibilities

Dear Registrant:

This letter is being sent to every entity in the United States registered with the Drug Enforcement Administration (DEA) to manufacture or distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance manufacturers and distributors to inform the DEA of suspicious orders in accordance with 21 CFR 1301.74(b)

In addition to, and not in lieu of, the general requirement under 21 USC 823, that manufacturers and distributors maintain effective controls against diversion, DEA regulations require all manufacturers and distributors to report suspicious orders of controlled substances. Title 21 CFR 1301.74(b), specifically requires that a registrant "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such a system. **Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders. Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system.**

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g. "excessive purchase report" or "high unit purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of an unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern is enough to trigger the registrants responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrants customer base and the patterns throughout the relevant segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused

controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communications with DEA that the registrant is actually characterizing an order as suspicious. Daily, Weekly, or monthly reports submitted by a registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USA 823 and 824, and may result in the revocation of the registrants DEA Certificate of Registration.

Section 13

Pharmacy Customers Advisory Notice of DEA Requirements

Notice of DEA Requirements

Every couple years a reminder letter should be sent to all wholesale pharmaceutical accounts to keep them aware of DEA requirements for distributors of controlled substances. This mail out can include a copy of written information we have received from DEA on the topic.

MIAMI-LUKEN, INC.
Full Service Drug Wholesaler

Miami Luken

March 19, 2013

To: Miami-Luken Pharmaceutical Customers
Subject: DEA Requirements- A Reminder

Referring to our prior letter sent out in January 2008, this is a reminder that DEA requirements for distributing controlled substances have not changed, and enforcement of regulations by DEA have become even more stringent.

The Controlled Substance Act of 1970 requires non-practitioners to make good faith inquiries whether persons are authorized to handle controlled substances and monitor ordering practices to determine whether registrants are making excessive or unusual purchases. Suspicious orders must be reported to the local Drug Enforcement Administration.

The following statements have been extracted from a DEA letter dated December 27, 2007 received by Miami-Luken, Inc. The letter from the **US Department of Justice, Drug Enforcement Administration** is enclosed in its entirety for your review.

- Distributors must maintain effective controls against diversion.
- Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substance are likely to be diverted from legitimate channels.
- Registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific and industrial channels may be failing to maintain effective controls against diversion.

Miami-Luken, Inc. must comply with DEA's request regarding our obligation to report suspicious orders. We ask that our customers cooperate with our sales force and answer any questions and provide any information that will honor DEA's request to obtain explanations for controlled substance purchases that vary significantly from normal trends.

Sincerely,

Anthony V. Rattini
President
Miami-Luken, Inc.

265 S. Pioneer Blvd. • Springboro, Ohio 45066
Phone (937) 743-7775 • Fax (937) 743-7780

U.S. DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

www.dea.gov Washington, D.C. 20537

MIAMI-LUKEN, INC
255 PIONEER BLVD
SPRINGBORO OH, 45066-0000

December 27, 2007

In reference to registration
PM0031550

Dear Registrant:

This letter is being sent to every entity in the United States registered with the Drug Enforcement Administration (DEA) to manufacture or distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 CFR 1301.74(b).

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The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unit purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of an unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communications with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by a registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.

For additional information regarding your obligation to report suspicious orders pursuant to 21 CFR 1301.74(b), I refer you to the recent final order issued by the Deputy Administrator, DEA, in the matter of Southwood Pharmaceuticals Inc., 72 FR 36487 (2007). In addition to discussing the obligation to report suspicious orders when discovered by the registrant, and some criteria to use when determining whether an order is suspicious, the final order also specifically discusses your obligation to maintain effective controls against the diversion of controlled substances.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

Section 14

On Site Investigation of Pharmacy Customers

On Site Investigation of Pharmacy Customers

In addition to the written profile of pharmacy customers that is filled out by the customer, shown in Section 2, Miami-Luken has engaged a private investigator to visit all accounts that purchase controlled substances. He will view the store operation and do a personal interview with each customer, store owner or store manager. These visits by the investigator started in April 2013.

Each site visit consists of:

- Approximately 45-90 min. sitting in the parking lot observing any suspicious activity, customers or anything out of order.
- Inside surveillance of the premises includes: observing the security and surveillance systems, DEA license, pharmacist's license, and state operating license (licenses must be posted on wall in clear view)
- Interview the staff in order to complete the evaluation form
- Check on the C IIs thru CVs and observe that they are stored according to DEA rules and regulations.
- Completing a site visit report form.

Date _____

Site Visit Report

Miami Luken
Rem Corporation

Compliance
account number _____

Name of account _____ Accepted Evaluation Report: Yes No

Is this a brick and mortar store: Yes No Description of site: _____

Was there a picture taken: Yes No

Who are your
primary/secondary
wholesalers?

Does the Pharmacist/Pharmacy/business have a current DEA number? Yes No

DEA number _____ (Optional)

Do they have a current State
license
number?_____

What percentage of your business is controlled substances? _____ Which controls?

Does this account have over the counter
products? Yes No _____

How long has this company been in business? _____

Sometime the sales representative will request a Utilization Report? Yes No

They will request to print at least the last 3 months? Yes No _____

Has anyone, in this location or another location affiliated with this business, ever had their state or DEA license disciplined, revoked or suspended? Yes No If yes, give explanation.

Is there a State inspection license/report or a DEA license posted in front for review? Yes No

Date _____

Site Visit Report

Hours store is in operation? _____

Do you sell online? Yes No If Yes, please give explantion: _____

_____

Name and address of the Company or Business:

_____

_____

_____

Jeffrey B. Chase, Compliance Representative for Miami Luken, has been at the above company/business and has completed a Pharmaceutical Evaluation. Please sign, giving title and date:

Signature/Title_____

Print Name_____ Date_____

Signature of Compliance Representative_____ Date _____

Site Visit Report

Date _____

This is an Acceptable Evaluation Report: Yes No If not an acceptable evaluation, please give explanation below:

Do we continue sales to this company/pharmacy? : Yes No

If no, give explanation.

Any suspicious or activity observed outside of the business:

MIAMI-LUKEN, INC.
Full Service Drug Wholesaler

Miami Luken

January 2008

To: Miami-Luken Pharmaceutical Customers
Subject: Recent DEA Requirements

The Controlled Substance Act of 1970 requires non-practitioners to make good faith inquiries whether persons are authorized to handle controlled substances and monitor ordering practices to determine whether registrants are making excessive or unusual purchases. Suspicious orders must be reported to the local office of the Drug Enforcement Administration.

The following statements have been extracted from a letter dated December 27, 2007 received by Miami-Luken, Inc. The letter from the **US Department of Justice, Drug Enforcement Administration** is enclosed in it's entirety for your review.

- Distributors must maintain effective controls against diversion.
- Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels.
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Miami-Luken, Inc. must comply with DEA's request regarding our obligation to report suspicious orders. We ask that our customers cooperate with our sales force and answer any questions and provide any information that will honor DEA's request to obtain explanations for controlled substance purchases that vary significantly from normal trends.

Sincerely,

Anthony V. Rattini
President
Miami-Luken, Inc.

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Phone (937) 743-7775 • Fax (937) 743-7798